

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Rebecca Gomez  
Application No. : 10/696,258 Confirmation No. : 7051  
Filed : October 28, 2003  
For : APPARATUS FOR TREATING HEMORRHOIDS AND SIMILAR  
AILMENTS  
Art Unit : 3769  
Examiner : David M. Shay

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.f.R. § 1.132 OF JEFFREY STEPHEN FREED

Sir:

I, Jeffrey Stephen Freed, hereby declare as follows:

1. That I am a citizen of the United States of America and that I reside in New York City, New York;

2. That I graduated cum laude from the State University of New York, College of Medicine, located in Brooklyn, New York with a Medical Doctor degree in the year 1970;

3. That I have been working in the field of medicine since 1970, and I currently specialize in proctology (the branch

of medicine dealing with the diagnosis and treatment of disorders of the colon, rectum, anus) and in general surgery. I have been an associate attending at Mount Sinai Medical Center since 1992, I have been Section Chief of Surgery at Bronx Veterans Hospital since 1979, I have been attending at Beth Israel Hospital since 1982, and I have been attending at Lenox Hill Hospital since 1987. I have been an associate clinical professor at Mount Sinai Medical Center since 1992;

4. That I am familiar with the claimed invention of the above-identified patent application Serial No. 10/696,258 (hereinafter referred to as "the Application"). I have reviewed the Application and the claims therein which are at issue;

5. That I know of no prior technology that is similar to the claimed invention or that provides relief of hemorrhoidal symptoms in the same manner. The claimed invention describes a unique shape and structure that has the ability to relieve mechanical stress on swollen tissue in the perianal area, thus providing rapid and immediate relief of hemorrhoidal symptoms. This may, for example, allow relief of symptoms without the use of potentially harmful medications, such as cortisone. Moreover, in addition to providing immediate relief of hemorrhoidal discomfort, the claimed invention can provide enhanced healing of hemorrhoids, thus obviating the need for a patient to undergo intrusive and painful procedures such as surgery;

6. That I have reviewed the following Rosenberg reference cited by the Examiner, *The Dilemma of Pilonidal Disease: Reverse Bandaging for Cure of the Reluctant Pilonidal*

Wound (hereinafter referred to as "Rosenberg"). It is my understanding that claims 13, 14, 21, 27, 33, 35-37 and 39 of the above-identified patent application have been rejected by the Examiner based on Rosenberg;

7. That I have compared the technology described by Rosenberg to the claimed invention of the Application. Rosenberg was published in 1977 and describes treating pilonidal disease, which is in contrast to the claimed invention that may be used to treat hemorrhoids. To treat pilonidal disease, Rosenberg describes strapping a patient's buttocks with adhesive strapping crossing the front of the abdomen. A marked difference between Rosenberg and the claimed invention is that the strapping of Rosenberg operates by pulling on tissue to change the anatomic nature of the presacraal skin and subcutaneous tissue of the buttocks to eliminate the natal cleft. The structure of the claimed invention, on the other hand, allows the claimed invention to operate in a different manner by distracting the buttocks to keep the skin in the perianal area from rubbing the inflamed tissue, thereby preventing the creation of further hemorrhoidal inflammation and its resultant pain, and allowing the hemorrhoid to experienced enhanced healing effects;

8. That the above-mentioned differences between Rosenberg and the claimed invention show the superiority of the claimed invention, in that the claimed invention can, for example, provide enhanced hemorrhoidal healing and symptoms relief not shown by Rosenberg;

9. That, in my opinion, the above-mentioned superiority of the claimed invention over Rosenberg, including the differences between the two devices, would not have been obvious to one skilled in art at the time the Application was filed, and that Rosenberg does not show the claimed invention;

10. That I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

10/10/09

Date



Jeffrey S. Freed